

**Remarks**

This Amendment After Final is in response to the Office Action dated **September 21, 2009**.

***Rejections***

***35 U.S.C. §102***

**Claim 1, 6-9, 11, 12 and 17**

In the Final Office Action, the rejection of claims 1, 6-9, 11, 12, and 17 under 35 U.S.C. §102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008) has been maintained.

Claim 1 has been amended to recite a dilatation balloon for use in combination with a catheter device, the balloon having waist portions, cone portions and a body portion. The balloon is formed of a first polymeric composition forming a first inner layer, and the balloon having a second outer layer formed on at least a portion of the first layer of said balloon, the second layer comprising a second polymeric composition which is crosslinked to form a compression region on at least a portion of said balloon, the second polymer composition is crosslinked on the waist portions, the cone portions, or both, and the second polymer composition on the body portion is uncrosslinked.

It is asserted in the Final Office Action, Response to Arguments, that:

As disclosed in Zamore and as stated in lines 25-32 of page 6 of Applicant's Remarks, Zamore does disclose that the balloon has one uncrosslinked layer (A). The body portion of this layer is uncrosslinked. Furthermore, the claims are drawn

to the second polymer composition being crosslinked on the waist portions, the cone portions, or both, and the body portion being uncrosslinked. The claims merely recite that the body portion is uncrosslinked and Zamore clearly discloses that the body portion of the first or inner layer (A) is uncrosslinked. Thus, at least a part of the body portion of the balloon of Zamore is uncrosslinked as the balloon has a body portion consisting of a first layer and a second layer and Zamore discloses that the first layer (A) is uncrosslinked.

Final Office Action, Response to Arguments, p. 10

Applicants have amended independent claim 1 to clarify that it is the outer balloon layer that is crosslinked on the waist and/or cone portions, but not on the body portion.

Zamore fails to disclose or suggest a balloon having an outer layer wherein the body portion is not crosslinked.

Claim 1 as amended is not anticipated by Zamore. “Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements “arranged as in the claim.” *Net MoneyIN v. Verisign*, 545 F.3d 1359, 88 USPQ2d 1751, 1756 (Fed. Cir. 2008) (string cites omitted).

Claims 6-9, 11 and 12 depend from claim 1 and are not anticipated by Zamore for at least the reasons that claim 1 is not anticipated by Zamore.

### **Claim 17**

Claim 17 has been amended in accordance with claim 1 and now recites a dilatation balloon having first and second waist portions, first and second cone portions and a body portion. The dilatation balloon is formed from a first polymeric composition that forms a first inner layer. The dilatation balloon further comprises a second outer layer on at least one of the first and second cone portions of the balloon formed from a second composition which is

crosslinked to form a compression region, the body portion of the balloon is uncrosslinked.

Claim 17 is not anticipated by Zamore for the same reasons that claim 1 is not anticipated by Zamore. Zamore fails to disclose or suggest a balloon having an outer layer wherein the body portion is not crosslinked.

Withdrawal of the rejection of claims 1, 6-9, 11, 12, and 17 under 35 U.S.C. §102(e) as being anticipated by Zamore (U.S. Patent Application No. 2004/0093008) is respectfully requested.

***35 U.S.C. §103(a)***

**Claims 1, 5-9, 11-13 and 17**

Claims 1, 5-9, 11-13 and 17 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008). It is asserted in the Office Action that:

Kaneko et al disclose the balloon substantially as claimed. Even though Kaneko et al disclose the second layer being formed on at least a portion of the first layer and the second composition being selected from the group of olefins or comprising polyethylene (lines 47-53 of column 6), Kaneko et al are silent on the specifics of the second polymeric composition being crosslinked to form a compression region and the body portion of the balloon being uncrosslinked. Zamore discloses a dilatation balloon with a first layer and a second layer on at least a portion of the first layer where the second polymeric composition is crosslinked. Zamore also discloses that the body portion of the balloon is uncrosslinked as shown in Figure 1 B where the body portion of the first or inner layer (A) is shown to be uncrosslinked.

Final Office Action, p. 4, bottom

As discussed above, both claims 1 and 17 have been amended to recite that it is the outer layer of the dilatation balloon wherein the cones and/or waist portions have been

crosslinked, but the body portion is uncrosslinked.

As both Kaneko et al. and Zamore are both silent as to an outer balloon layer being crosslinked on the cone and/or waist portions of the balloon, but not on the body, no *prima facie* showing of obviousness has been made with respect to claims 1 and 17 as amended.

In order to establish *prima facie* obviousness, “... the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.” *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP 2142.

Claims 5-9 and 11-13 depend from claim 1 and are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 1, 5-9, 11-13 and 17 under 35 U.S.C. §103(a) as being obvious over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No. 2004/0093008) is respectfully requested.

### **Claims 5 and 13**

Claims 5 and 13 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. It is asserted in the Final Office Action that:

Zamore discloses the balloon substantially as claimed. However, Zamore is silent on a tie layer between the first layer and the second layer and a tie layer between the balloon and the catheter shaft. Kaneko et al disclose a tie layer (17) between a first layer (18) and the second layer (16) and a tie layer between the balloon and the catheter shaft.

Final Office Action, p. 6, no. 5

Claims 5 and 13 depend from claim 1.

As discussed above, the combination of Zamore and Kaneko et al. fail to render claim 1 obvious because the combination lacks the requisite disclosure or suggestion of an outer balloon layer that is crosslinked on the cones and/or waist portions but is not crosslinked on the balloon body for the purpose of providing a compression region for facilitating collapse and refolding of the balloon in a body lumen after use.

Claims 5 and 13 are not obvious over Zamore in view of Kaneko et al. for at least these reasons.

Withdrawal of the rejection of claims 5 and 13 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. is respectfully requested.

**Claim 10 – Zamore and Smith et al.**

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Smith et al (U.S. Patent No. 6,083,587).

Claim 10 depends from claim 1. Claim 1 is not obvious over Zamore as discussed above. Zamore fails to disclose or suggest a balloon outer layer that is crosslinked on the cones and/or waist portions but is not crosslinked on the balloon body for the purpose of providing a compression region for facilitating collapse and refolding of the balloon in a body lumen after use.

In the Final Office Action, Smith et al. is combined for multilayer balloon structures having a tie layer between first and second balloon layers. See Final Office Action, p. 7, no. 6.

However, combining a tie layer with Zamore still fails to render claim 1 obvious because the combination still lacks the requisite disclosure or suggestion of crosslinking an outer

balloon layer on the cones and/or waist portions, but not on the body portion of the outer layer.

Claim 10 is not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claim 10 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Smith et al. is respectfully requested.

**Claim 10 – Kaneko et al., Zamore and Smith et al.**

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al in view of Zamore as applied to claim 6 above, and further in view of Smith et al (U.S. Patent No. 6,083,587). Kaneko et al and Zamore disclose the balloon.

Claim 10 depends from claim 1. Claim 1 is not obvious over Kaneko et al. and Zamore as discussed above. The combination fails to disclose or suggest a balloon having an outer layer that is crosslinked on the cones and/or waist portions but is not crosslinked on the balloon body for the purpose of providing a compression region for facilitating collapse and refolding of the balloon in a body lumen after use.

Combining the tie layer of Smith et al. with Kaneko et al. and Zamore still fails to render claim 1 obvious for the reasons set forth in the paragraph above.

Claim 10 is not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claim 10 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore and Smith et al. is respectfully requested.

**Claims 14-16 – Zamore, Kaneko et al. and Samuelson et al.**

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683).

Claims 14-16 depend from claim 1. Claim 1 is not obvious over Zamore in view of Kaneko et al. as discussed above. The combination fails to disclose or suggest a balloon having an outer layer that is crosslinked on the cones and/or waist portions but is not crosslinked on the balloon body for the purpose of providing a compression region for facilitating collapse and refolding of the balloon in a body lumen after use.

Combining the tie layer of Samuelson et al. (discussed with respect to claim 10 above) with Zamore and Kaneko et al. still fails to render claim 1 obvious for the same reasons set forth in the paragraph above.

Claims 14-16 are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 14-16 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Kaneko et al. and Samuelson et al. is respectfully requested.

**Claims 14-16 – Kaneko et al., Zamore and Samuelson et al.**

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al in view of Zamore as applied to claim 13 above, and further in view of Samuelson et al. (U.S. Patent No. 6,464,683).

Claims 14-16 depend from claim 1. Claim 1 is not obvious over Kaneko et al. and Zamore as discussed above. The combination fails to disclose or suggest a balloon having an outer layer that is crosslinked on the cones and/or waist portions but is not crosslinked on the

balloon body for the purpose of providing a compression region for facilitating collapse and refolding of the balloon in a body lumen after use.

Combining the tie layer of Samuelson et al. (discussed with respect to claim 10 above) with Zamore and Kaneko et al. still fails to render claim 1 obvious for the same reasons set forth in the paragraph above.

Claims 14-16 are not obvious over this combination for at least these reasons.

Withdrawal of the rejection of claims 14-16 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore and Samuelson et al. is respectfully requested.

**CONCLUSION**

Claims 1 and 5-17 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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